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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,508	10/05/2005	Sylvain Orenga	125292	2414

25944 7590 10/17/2008

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EXAMINER	
HOBBS, LISA JOE	
ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
10/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,508	ORENGA ET AL.	
	Examiner	Art Unit	
	Lisa J. Hobbs	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 6-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 07 April 2003. It is noted, however, that applicant has not filed a certified copy of the French patent application as required by 35 U.S.C. 119(b).

Claim Status

Claims 1, 3, 6-16 are active in the case. Claims 2, 4-5, 17-19 have been cancelled by amendment. Claims 1, 3, 6-16 are under examination; no claims are withdrawn as drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3, with dependent claims 6-11, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 depends from cancelled claim 2, thus the metes and bounds of the invention are unclear for claim 3 which recites "said bacterium". For the purposes of the instant examination, the examiner has interpreted the dependency of claim 3 to have moved to claim 1 since the recitation of "Salmonella" further limits the genus of "bacterium" from claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 6-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 5,854,011) in view of Cooke et al. ((1999) Appl. Env. Microbiol. 65(2): 807-812), Kardos et al. ((2000) Toxicological Sciences 58: 118-126), Sondegaard et al. ((2001) Chem. Eng. 7(11): 2324-2331), Merrer et al. ((1997) Bioorg. Med. Chem. 5(3): 519-533) and Gilbert et al.

(WO 2002/40706). Chen et al. teach a composition and method for detecting the presence or amount of yeasts and molds in a test sample is presented. The composition contains a substrate and an inhibitor for an aminopeptidase. The substrate has a signal moiety capable of providing a detectable signal when cleaved by an aminopeptidase in yeasts or molds. The aminopeptidase inhibitor serves to reduce the endogenous aminopeptidase activity in the test sample. The method to detect yeasts or molds in a sample includes inoculating a test sample with the disclosed composition, incubating the sample and observing any detectable signal that indicates the presence of yeasts or molds (abstract). They teach a variety of organisms (Tables I and II), substrates (Table III), inhibitors (col. 16 line34 to col. 17 line 27), etc., with which this method can be practiced using the medium as described. They disclose the importance of such a medium and method, teaching that "yeast or mold contamination in food and other commodities can result in substantial economic losses for the producer, the processor, and the consumer. Rapid and accurate determinations of yeast and/or mold contamination in a commodity (such as, food ingredients, processed foods, and beverages), are important for the production of high-quality food products in the food industry" (col. 1 lines 24-31). They also disclose the various components, detection and inhibition: "accordingly, a medium is disclosed for detecting yeasts and molds in a biological sample. In certain preferred embodiments, the medium provides effective results by employing a newly identified ubiquitous enzyme in yeasts and molds: aminopeptidase. The medium is preferably provided in combination with an inhibitor for the aminopeptidase enzyme. The inhibitor is provided at a level that reduces endogenous activity in test samples, but which does not impair the activity in yeasts or molds. In addition, buffer ingredients, carbohydrates, amino acids, trace elements, salts, and growth stimulators provided in

the medium allow sufficient growth of the organism, so that the detectable signal in the sample due to hydrolysis of aminopeptidase substrates is more effectively observed" (col. 3 lines 37-50). They do not disclose the use of esterases, osidases, Salmonella or the use of esterase or osidase inhibitors.

Cooke et al. teach the use of a medium to detect Salmonella esterases (abstract) which provides chromogenic substrates for the detection of the Salmonella in a sample to be tested and report that the disclosed medium and chromogenic substrate was extremely successful in detecting the more common Salmonella serotypes reported to the Public Health Laboratory Service (p. 812, col. 1). They do not teach the use of inhibitors, osidases, or Candida detection. Kardos et al. teach the use of organophosphates to inhibit esterases and methods for determining the amounts necessary for inhibition (abstract). They do not teach a chromogenic media, osidases, or lower organisms. Sondegaard et al. and Merrer et al. teach the use of azasugars as potent osidase inhibitors of "intense current interest" (Sondergaard et al. p. 2324, col. 1). They do not teach chromogenic media or the in vivo use of the inhibitors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the media disclosed by Chen et al., which provides a fast and reliable way to determine the presence of harmful microorganisms in a sample, while providing a concomitant inhibition of endogenous activity in the sample, with known pathogenic organisms such as Candida and Salmonella, known enzymes such as esterases and osidases, and known inhibitors such as organophosphates and azasugars. One would have a reasonable expectation of success as evidenced by Gilbert et al., who teach chromogenic and fluorogenic media, similar to Chen et

al. excepting the inhibitor, for the identification of aminopeptidases, esterases, and osidases from a range of organisms which include Salmonella and Candida (p. 1).

Response to Arguments

Applicant's arguments filed 27 June 2008 have been fully considered but they are not persuasive. Applicant has limited the independent claim, claim 1, to the genus of bacteria and removed other microorganisms from the claim language, thus applicant argues that the Chen et al. reference no longer applies to the instant claims. Applicant also quotes portions of Chen et al. stating that the invention is drawn to a new discovery: the presence of aminopeptidases in yeasts and molds and that the media of Chen et al. includes media which contain inhibitors for specific heterotrophic bacteria, not yeasts and molds. However, aminopeptidases were known to be present in many organisms, including many bacteria and higher organisms such as humans and the concept of Chen et al., a reporter assay using a known enzyme linked to a signal which assay comprises an inhibitor for enzymes in the test sample which are not of interest, is still applicable and would have been known to one of skill in the art.

Chen et al. state (col. 3, lines 20-30) that "a medium is provided which contains one or more aminopeptidase substrates; these substrates have a nutrient moiety and a detectable moiety linked together by a covalent peptide bond. When the substrate is hydrolyzed by aminopeptidase to create a separate detectable moiety, it causes or produces a detectable signal. Thus, these substrates produce detectable signals when any one of the aminopeptidases is present in the medium. An aminopeptidase specific inhibitor can be included in the medium to prevent signal interference due to the endogenous aminopeptidase activity in the biological matrix." As well,

they teach that the concept of testing for microorganisms using enzymes known to be present in those microorganisms, not just yeasts and molds, is known to those of skill in the art, "[o]ne approach to test the presence of a microorganism or a group of microorganisms is to take advantage of the metabolic and physiological characteristics of specific microbes. Specific microorganisms derive their nutrients from an array of sources, some of which may be unique to a particular microorganism or group of microorganisms. Many enzymes have been identified which are specific to particular groups or species and others likely will be identified in the future" (col. 17, lines 44-52).

Kapeller-Libermann et al. (US 2002/0076796 A1) and McCarthy (US 2001/0041353 A1) both teach that at the time of the invention it was well-known that Salmonella possessed aminopeptidases. Kapeller-Libermann et al. state that "[a] variety of aminopeptidases have been identified from a wide variety of tissues and organisms, including zinc aminopeptidase and aminopeptidase M from kidney; arginine aminopeptidase from liver; aminopeptidase N.sup.b from muscle; leucine aminopeptidase (LAP) from lens and kidney; aminopeptidase A (xerB gene product) from E. coli; yscl APE1/LAP4 and aminopeptidase A (pep4 gene product) from S. cerevisiae; LAP from Aeromonas; dipeptidase from mouse ascites; methionine aminopeptidase from Salmonella, E. coli, S. cerevisiae and hog liver; and D-amino acid aminopeptidase from Ochrobactrum anthropi SCRC C1-38" [0008], while McCarthy teaches "[i]t is well known in the art that a methionine at the N-terminal position can be enzymatically cleaved by the use of the enzyme methionine aminopeptidase (MAP). MAP has been cloned from E.coli…and Salmonella typhimurium and its in vitro activity has been demonstrated on recombinant proteins" [0152]. It would be obvious for one of skill in the art to use enzymatic markers and, specifically,

aminopeptidases, as taught by Chen et al., to detect microorganisms of interest, such as Salmonella which Kapeller-Libermann et al. and McCarthy teach was a well-known possessor of aminopeptidases. As discussed previously, Cooke et al. teach a medium for detecting Salmonella esterase and the methods of Chen et al. would be readily applied to this type of enzyme as well as aminopeptidases.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday to Friday, 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh